DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
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Dietary Supplements; Center for Food Safety and Applied Nutrition Strategy; Public Meeting

The Association of Food and Drug Officials (AFDO) is a non-profit, professional association consisting of state, federal, and local regulatory officials as members, with industry representatives participating as associate members. From its inception almost 103 years ago, AFDO has recognized the need for uniform laws and regulations governing foods and drugs and has actively promoted uniformity and cooperation within the regulatory arena. AFDO strongly supports FDA's desire to develop effective strategies for achieving proper regulation of dietary supplements.

With respect to the enhancement of consumer safety, FDA needs to follow the recommendations of the President's Commission on Dietary Supplement Labels and address areas where labeling is inadequate for safe use.

Some dietary supplements, particularly products contain botanical ingredients, have potent pharmacological activity resulting in potential drug interactions with both over-the-counter (OTC) and prescription drugs and other incompatibilities such as with alcohol. In addition, some supplements, notably those with either sedating or stimulant actions, have the potential for abuse. Consumers need to be aware, not only of potential drug interactions, but that exceeding the recommended dosage or taking some supplements for extended periods can be harmful. Women who are pregnant, trying to conceive, or are on estrogen therapy should not consume products that contain melatonin or steroid hormone precursors like DHEA or androstenedione. Supplements containing ingredients with psychotropic effects like St. John's Wort, valerian, and kava kava need informative labeling to assure that consumers do not suffer adverse effects from using these products in combination with prescription psychotropic drugs. In addition, many products are contraindicated for persons with underlying medical conditions like hypertension and diabetes.

FDA, with industry input, must answer the question, "Where is the appropriate place for consumers to receive accurate information to insure safe use of dietary supplements, from print media and advertising, from manufacturers of OTC and prescription drugs which may interact with supplements, or from manufacturers of dietary supplements in the form of additional labeling information?". A product is misbranded if its label fails to disclose material facts or consequences of customary use. Does the lack of adequate warnings on dietary supplements fall into the category of failing to disclose material facts or consequences of customary use?

Many consumers, including many senior citizens, take a wide variety of prescription and OTC drugs along with dietary supplements without discussing the use of supplements with their doctors or fully understanding the possible interactions, contraindications, or symptoms of adverse reactions. To ensure safe use, these individuals need to be informed to talk to their

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doctors when taking supplements and provided with information on possible interactions, contraindications, or symptoms of adverse reactions from supplements. The President's Commission pointed to labeling as the appropriate mechanism. FDA has identified enhancement of consumer safety as its first priority for dietary supplement safety and the development of health-related product labeling regulations, its second priority. AFDO concurs with this important emphasis and hopes that the issues raised by the President's Commission with respect to additional label information and warnings remains the highest priority.

AFDO has praised FDA's new labeling regulations, but they really don't go far enough. If a product is to be used in a fashion similar to an OTC or prescription drug, which many supplements are (for example, "dieter's" teas for constipation or St. John's Wort for mild to moderate depression), then an accurate statement of the potency of the active ingredients must be disclosed. Knowing the quantity of the botanical present does not necessarily bear any declaration of the amount of active ingredient, which is the overriding issue for appropriate use.

In addition, AFDO feels that some products should not be provided to infants. Florida had one death associated with an infant being given Echinacea instead of traditional therapies. Some of the herbal books declare that Echinacea should not be used by children under the age of two. Again, whose responsibility is it to provide consumers with this information, which, unfortunately, is not uniform source to source?

AFDO previously testified, and continues to believe, that FDA and the industry need to jointly approach these issues from a stance that solutions in this area will benefit industry by assuring that consumers have educated access to dietary supplements while protecting the industry from product liability due to inadequate label information for safe use. One mechanism would be the development of a compendium on dietary supplements beginning with herbals with pharmaceutical properties. This compendium would include possible interactions with other supplements, OTC, and prescription drugs, adverse reactions, and contraindications. The compendium could also provide information on the levels of active ingredients expected to be effective. Currently FDA's website provides limited information on a few dietary supplements and refers consumers to Office of Dietary Supplements or Institute on Aging at the NIH. Searching the Office of Dietary Supplements database is not a viable option for most of the public, particularly elderly persons.

On March 26, 1999, the Canadian Minister of Health announced the creation of the Office of Natural Health Products that will provide Canadian consumers with assurance of safe products while continuing to ensure access to a full range of health products. AFDO recommends that FDA examine the system used by the Canadian Office of Natural Health Products and perhaps partner with this Office to allow eventual harmonization of both countries systems to assure access to and the safety of a full range of dietary supplements and natural health products.

AFDO believes that the FDA should make finalization of Good Manufacturing Practices regulations a high priority. While the industry has provided guidance through voluntary GMP's, it is important that the FDA finalize uniform standards for GMP's, which can be adopted by states to ensure national uniformity. These GMP's should give special emphasis to quality of raw ingredient, impurities or contaminants, and levels of active ingredients. This emphasis is essential since much of the raw material is produced outside of this country and therefore outside the oversight of FDA.

FDA also needs to actively enforce its laws and regulations relating to dietary supplements that protect consumer health. AFDO understands the tremendous workload that DSHEA created for the agency at the same time other critical issues were on the table. However, the explosion of the use of dietary supplements, which is projected to increase even more, mandates that resources to address these issues be given a very high priority within FDA. AFDO pledges its support to FDA with respect to integrating dietary supplement activities with state programs.

While it is essential for consumers to have access to dietary supplements, it is incumbent on government with industry's input to ensure that consumers have accurate and appropriate information on products to enable safe and knowledgeable use.

The following is provided in response to specific questions:

1. Are there other objectives that the FDA strategy should include?

AFDO feels that particularly with dietary supplements a strong educational component is required. This educational component should have emphasis for medical and health professionals as well as consumers.

2. Are the criteria for prioritizing the tasks within the supplement strategy appropriate?

AFDO has strongly responded to this in its opening remarks that adequate product labeling information to ensure safe use in conformance with the recommendations of the President's Commission on Dietary Supplement Labels has to be the highest priority.

3. What factors should FDA consider in determining how best to implement a task?

The mechanism for implementing a task will depend on the task. If it is a task, which necessitates national uniformity in application by other state and local programs, then FDA must choose the regulation route so that states can adopt them as state rules. If, on the other hand, the task is interpretive, guidance documents will suffice. The industry can assist the FDA in determining where uniformity will be needed.

4. What tasks should be included under the various dietary supplement program elements in the CFSAN 1999 Program Priorities document?

Adequate label information for safe use of products, good manufacturing practices, and education of medical and health professionals, as well as consumers, are the tasks AFDO feels are most important.

5. Are there current safety, labeling, or other marketplace issues that FDA should address quickly through enforcement actions to ensure...products on the market are safe and truthfully and not misleadingly labeled?

AFDO has responded to this question in the body of its opening remarks. Clearly the issue of current inadequate label information for safe, informed use is paramount.

6. Toward what type of area of research on dietary supplements should FDA allocate its research resources?

Research resources should be directed toward product integrity and safety.

7. Given FDA's limited resources, what mechanisms are available, or should be developed, to leverage FDA's resources to meet effectively the objective of the strategy?

FDA can leverage resources by use of JIFSAN and by utilizing industry and state programs where appropriate to provide input on issues, extend enforcement strategies, and provide information on prioritization of problem areas.

AFDO appreciates the opportunity to comment on this important matter.